

### REMARKS

Claims 1, 2, 19, 20 and 24 have been canceled without prejudice or disclaimer. Claims 48-78 have been added and therefore are pending in the present application. Claims 48-78 are supported by claims 1-47.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

#### I. The Restriction and Election of Species Requirements

The Office Action made restriction and election of species requirements. As provided therein, Applicants provisionally elected with traverse the invention of the protease of SEQ ID NO: 1 and position 171 as the species. Applicants confirm this election. Applicants reserve the right to file continuing applications directed to non-elected subject matter.

#### II. The Objection to the Specification

The Office objected to the specification because the claims do not have designations that describe their subject matters according to the requirements of 37 CFR 1.821.

The claims have been rewritten as claims 48-78 to address this objection. Therefore, this objection has been overcome.

#### III. The Objection to Claims 2, 19, 20 and 24

The Office objected to claims 2, 19, 20 and 24 because of informalities. The claims have been rewritten as claims 48-78 to address this objection. Therefore, this objection has been overcome.

#### IV. The Rejection of Claims 1, 2, 19, 20 and 24 under 35 U.S.C. 112

Claims 1, 2, 19, 20 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

As set forth in Federal Circuit decisions, a specification complies with the written description requirement if it provides "a precise definition, such as by structure, formula, chemical name, or physical properties of the claimed subject matter sufficient to distinguish it from other

materials." See, e.g., *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398, 1404 (Fed. Cir. 1997); *Enzo Biochem v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002).

The claimed invention is drawn to protease having a specific structure, i.e., an amino acid sequence which is at least 90% homologous to SEQ ID NO: 1. The specification fully describes the proteases of the present invention. Applicants therefore submit that the specification demonstrates that Applicants had possession of the claimed invention at the time the application was filed.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **V. The Rejection of Claims 1, 2, 19, 20 and 24 under 35 U.S.C. 112**

Claims 1, 2, 19, 20 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation of modified subtilases having no more than ten amino acid sequence modifications at positions selected for modification numbered according to the amino acid sequence of the mature subtilisin BBPN' set forth in SEQ ID NO: 2, does not reasonably provide enablement for the preparation of modified, generic proteases having as many as 149 amino acid sequence modifications at positions recited in the claims if numbered according to no particular amino acid sequence. This rejection is respectfully traversed.

It is well settled that "[t]he first paragraph of section 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance." *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). Moreover, "a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of section 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 169 USPQ at 369.

"The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art ... The test is not quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation

should proceed to enable the determination of how to practice a desired embodiment of the invention claimed ..." *Ex parte Jackson*, 217 U.S.P.Q. 804 (Bd. Pat. App. 1982).

It is also well settled that an assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (C.C.P.A. 1974). See also *U.S. v. Telectronics*, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988); *In re Bowen*, 181 U.S.P.Q. 48 (C.C.P.A. 1974); *Ex parte Hitzeman*, 9 U.S.P.Q.2d 1821 (BPAI 1988).

Moreover, in the absence of any evidence or apparent reason why compounds do not possess the disclosed utility, the allegation of utility in the specification must be accepted as correct. *In re Kamal*, 158 U.S.P.Q. 320 (C.C.P.A. 1968). See also *In re Stark*, 172 U.S.P.Q. 402, 406 n. 4 (C.C.P.A. 1972) (the burden is upon the Patent Office to set forth reasonable grounds in support of its contention that a claim reads on inoperable subject matter).

In the present application, the specification describes examples of proteases of the present invention. Furthermore, the specification contains an extensive disclosure of techniques which are well known in the art and indeed routine for persons of ordinary skill in the art for identifying other proteases of the present invention. It is well within the skill of the art to isolate and identify the claimed proteases using the Applicants' disclosure.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **VI. The Rejection of Claims 1, 2, 19, 20 and 24 under 35 U.S.C. 112**

Claims 1, 2, 19, 20 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The claims have been rewritten as claims 48-78 to address this rejection. Applicants therefore submit that this rejection has been overcome.

#### **VII. The Rejection of Claims 1, 2, 19, 20 and 24 under 35 U.S.C. 102**

Claims 1, 2, 19, 20 and 24 are rejected under 35 U.S.C. 102 as being anticipated by Servant et al. (the amino acid sequence of UniProt Accession No. Q9S3L6 (1999)), Wati et al. (UniProt Accession No. O54327 (1998)), Davail et al. (1992), Narinx et al. (1992) and Miyazaki et al. (1990). These rejections are respectfully traversed.

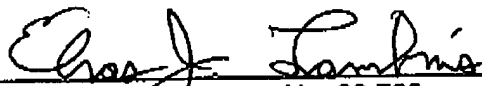
The cited references disclosed various proteases. However, none of the references disclose or suggest the protease variants claimed herein.

For the foregoing reasons, Applicants submit that the claims overcome these rejections under 35 U.S.C. 102. Applicants respectfully request reconsideration and withdrawal of the rejections.

#### VIII. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,



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